REMARKS

In the Office Action dated November 29, 2007, the Examiner rejected claims 12, 14 and 17 under 35 U.S.C. § 101; rejected claim 17 under 35 U.S.C. § 112, second paragraph; rejected claims 1-10, 12, and 14-17 under 35 U.S.C. § 102(b) as being anticipated by WO 88/55166 to Sternby ("Sternby"); and rejected claim 15 under 35 U.S.C. § 103(a) as being unpatentable over Sternby in view of U.S. Patent No. 6,284,141 to Shaldon ("Shaldon").

By this Reply, Applicant has canceled claims 12, 14, and 17 and has amended claims 1, 6, and 16. Accordingly, claims 1-10, 15, and 16 are currently pending in this application. No new matter has been added by this Reply.

REJECTIONS UNDER § 101

In the Office Action, the Examiner rejected claims 12 and 14 under 35 U.S.C. § 101 as being directed to non-statutory subject matter and claim 17 as being an improper process claim. While Applicant does not agree with the Examiner's rejection of claims 12 and 14 and characterization of claim 17, in order to advance prosecution of this application, Applicant has canceled claims 12, 14, and 17, thereby rendering these rejections moot. Accordingly, Applicant requests that the Examiner withdraw these rejections.

REJECTION UNDER § 112

In the Office Action, the Examiner further rejected claim 17 under 35 U.S.C. § 112, second paragraph, as failing to set forth the subject matter which applicant regards as his invention. Applicant disagrees with the Examiner's rejection of claim, however, in order to advance prosecution of this application, Applicant has canceled

claim 17, thereby rendering this rejection moot. Accordingly, Applicant asks that the Examiner withdraw the rejection.

REJECTION UNDER § 102(b)

In the Office Action, the Examiner also rejected claims 1-10, 12, and 14-17 under 35 U.S.C. § 102 as being anticipated by Sternby. Applicant traverses and requests the withdrawal of the § 102(b) rejection of claims 1-10, 15, and 16 (claims 12, 14, and 17 having been canceled), because Sternby does not anticipate these claims.

In order to properly anticipate Applicant's claims under § 102, a single prior art reference must disclose each and every element of the claim at issue, either expressly or under principles of inherency. Further, "[t]he identical invention must be shown in as complete detail as is contained in the . . . claim." See M.P.E.P. § 2131. Also, "[t]he elements must be arranged as required by the claim." Id. Applicant respectfully requests withdrawal of the rejection for the reasons provided below.

Applicant submits that Sternby does not disclose each and every element of independent claims 1, 6, and 16 as amended. In particular, while the claimed invention measures treatment efficiency in relation to the potential cleaning capacity (K_{eff}, K), a theoretical maximum efficiency, Sternby measures the treatment efficiency in relation to the patient's size.

In addition, Sternby discloses "a whole body clearance K defined as the ratio between urea mass removal rate and mean urea concentration c_m in the body." Sternby, pg. 10, ll. 18-20. Sternby, however, does not disclose the claimed method or procedure for determining a whole body clearance. Sternby provides a conceptual explanation of a whole body clearance (denoted as K in Sternby). The mean urea concentration c_m,

referenced in equations (4) and (5) on page 10 of Sternby, is a parameter that cannot be directly measured in the body. Thus, equation (4) in Sternby cannot be used to calculate a whole body clearance using a directly measured c_m of a patient.

Moreover, Sternby does not disclose "the whole body clearance ratio being a dimensionless positive numeral smaller than one." as recited in independent claims 1, 6, and 16. Sternby is directed at calculating a treatment dosage (Kt/V), which is derived by accumulating (or summing up) a momentary treatment efficiency (see Sternby, pg. 13, ll. 12-17). Also, the treatment efficiency measurement of Sternby, may be determined continuously or repeatedly throughout the treatment. Therefore, because the treatment dosage increases over time, the dosage and related ratio may theoretically attain any number, including numbers larger than one. The dosage is also associated with a dimension of per-second magnitude. Thus, for at least these reasons, Sternby does not disclose a "whole body clearance ratio being a dimensionless positive numeral smaller than one."

Also, in the solution of Sternby, the dosage at a particular point in time depends on the size of the patient relative to the dialyzer. When the dosage is checked, if it is found that the dosage is too low, the treatment may simply be prolonged in order to increase the total dosage. The ratio calculated in the present application, however, cannot be increased by prolonging the treatment. Instead, various alternative measures may be taken to improve the patient's response to the treatment, thus ensuring that the whole body clearance ratio remains smaller than one.

For at least the aforementioned reasons, the § 102(b) rejection of independent claims 1, 6, and 16, as amended, should be withdrawn and claims 1, 6, and 16 allowed.

Further, claims 2-5 and 7-10, are allowable at least due to their dependence from either claim 1 or claim 6, and due to their additional recitations of novel subject matter.

REJECTION UNDER § 103(a)

In the Office Action, the Examiner also rejected claim 15 under 35 U.S.C. § 103(a) as being unpatentable over <u>Sternby</u> in view of <u>Shaldon</u>.

Claim 15 ultimately depends from either independent claim 1 or 6. As discussed above in connection with claims 1 and 6, <u>Sternby</u> discloses "a whole body clearance K defined as the ratio between urea mass removal rate and mean urea concentration c_m in the body." <u>Sternby</u>, pg. 10, ll. 18-20. <u>Sternby</u>, however, does not disclose "the whole body clearance ratio being a dimensionless positive numeral smaller than one." <u>Shaldon</u> discloses efficiency or clearance curves (see <u>Shaldon</u>, Figs. 1 and 2), but the efficiency curves have a dimension of inverse time (i.e., hr^{-1}) and increase above a value of one. Thus, <u>Shaldon</u> does not cure the deficiencies of <u>Sternby</u> discussed above. Therefore, dependent claim 15 is allowable over the cited references and the § 103(a) rejection of dependent claim 15 should be withdrawn.

CONCLUSION

In view of the foregoing amendments and remarks, Applicant respectfully requests reconsideration and reexamination of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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Dated: February 26, 2008   By:_____
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